

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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|--|--|--|-----------------------|
| Applicant's or agent's file reference P03264 | FOR FURTHER ACTION | | See Form PCT/IPEA/416 |
| International application No. PCT/US2004/011188 | International filing date (day/month/year) 12.04.2004 | Priority date (day/month/year) 11.04.2003 | |
| International Patent Classification (IPC) or national classification and IPC A61F9/01 | | | |
| Applicant BAUSCH & LOMB INCORPORATED ET AL. | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | | |
| Date of submission of the demand 08.10.2004 | | Date of completion of this report 16.09.2005 | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016 | | Authorized Officer Knüpling, M Telephone No. +31 70 340-2891 | |



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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-28 as originally filed

Claims, Numbers

1-53 as originally filed

Drawings, Sheets

1/15-15/15 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
 - ☒ claims Nos. 8
- because:
- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
 - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - ☒ no international search report has been established for the said claims Nos. 8
 - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
 - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
 - ☐ See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|--------------------------|
| Novelty (N) | Yes: Claims | 5,15,25 |
| | No: Claims | 1-4,6,7,9-14,16-24,32-53 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 5,15,25 |
| Industrial applicability (IA) | Yes: Claims | 1-7,9-53 |
| | No: Claims | |

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item III.

The method according to claim 8 comprises the step of engaging a therapeutic laser to apply a treatment to a patient's eye, where engaging is interpreted as meaning activating. Laser treatment of an eye is regarded as a surgical treatment in the meaning of Rules 39.1 (iv) and 67.1 (iv) PCT. Thus no search was carried out for this claims (Article 17(2)(a)(I) PCT) and no written opinion about novelty, inventive step or industrial applicability of these claims will be given (Article 34(4)(a)(I) PCT).

Re Item V.

V 1.

The following documents are referred to in this communication:

- D1 : US 6 159 205 A (WOODWARD BENJAMIN W ET AL) 12 December 2000 (2000-12-12)
- D2 : US 2002/075451 A1 (RUIZ LUIS ANTONIO) 20 June 2002 (2002-06-20)
- D3 : GATINEL DAMIEN ET AL: "Three-dimensional representation and qualitative comparisons of the amount of tissue ablation to treat mixed and compound astigmatism." JOURNAL OF CATARACT AND REFRACTIVE SURGERY. NOV 2002, vol. 28, no. 11, November 2002 (2002-11), pages 2026-2034, XP002293300 ISSN: 0886-3350

V 2. Independent claims 1, 6, 32

V 2.1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 6, and 32 is not new in the sense of Article 33(2) PCT.

V 2.2

Referring to claim 1, document D2 discloses (the references in parenthesis applying to this document):

An algorithm to aid in the selection of a treatment plan for vision correction in a patient's eye, comprising:

- obtaining selected diagnostic input data types about the patient's eye (para. [0129], l. 1 - 5);
- parameterizing the input data to classify the patient's eye into one of a predetermined plurality of classification sets (para. [0131], l. 1 - 9 referring to an irregular eye and para. [0138], l. 7 - 14 referring to a regular eye and to an astigmatic cornea);
- determining a viable plurality of treatment algorithms for potentially correcting the patient's vision based upon the classification (para. [0143], first sentence; para. [0145]; para. [0146]);
- presenting a respective plurality of treatment plans based upon the treatment algorithms for prospective selection of one of the treatment plans (para. [0130], l. 1 - 6; para. [0145]; para. [0146]).

V 2.3

Referring to claim 6, D2 further discloses treatment algorithms utilizing one or more default parameters (para. [0129], l. 9 ff: 'The spherical fit is performed along a chosen axis by the user or is based on a pre-configured default axis') which can be modified (same passage). Other treatment parameters can be interactively modified (same passage). Obviously, since parameters can be modified, treatment plans are re-processed and re-presented for further review.

V 2.4

The same reasoning applies, *mutatis mutandis*, to corresponding apparatus claim 32.

V 2.5

Consequently, the subject-matter of claims 1, 6, and 32 lacks novelty (Article 33(2) PCT).

V 3 Dependent claims

Dependent claims 2 - 5, 8 - 14, 16 - 31, 33 - 53 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see documents D1 - D3 and the

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(SEPARATE SHEET)**

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corresponding passages cited in the search report.

Claim 15, for which no document was cited, is rendered obvious by D1, which discloses preference settings including treatment zones excluding the central optical zone where treatment is not desired (D1, col. 17, l. 27 - 28).

V 4 Further remarks

Claim 1 does not meet the requirements of Article 6 PCT since it is unclear if the claim is directed to an activity (method) or an entity (computer program product). According to the The American Heritage Dictionary of the English Language, Fourth Edition, an algorithm is a step-by-step problem-solving procedure, especially an established, recursive computational procedure for solving a problem in a finite number of steps.